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453 '99 SEP -8 AIO :01

August 30, 1999

FDA Commissioner David Kessler
Dockets Branch
FDA
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket 96P0215

Dear Commissioner Kessler,

On 18 September 1991, my wife, Nohemi Carter and I watched a Norplant Video Film and read the Norplant brochure. My wife then had 6 Norplant capsules implanted under the skin on the inside of her left upper arm, at a cost of \$500. The Norplant Video Film and the Norplant brochure explained that my wife may have some side effects which might develop such as slight weight gain, an insignificant increase in her menstrual bleeding and possible increase in acne. All of these possible side effects, we were assured would be insignificant compared to the 5 years of freedom from other forms of contraceptive protection.

My wife was 28 years old, 5 foot 2 inches tall, and weighed about 120 pounds. Within one month she weighed 146 pounds. And within 9 months, her body weight had increased 50%, from 120 to 180 pounds. An increase of 60 pounds! Her doctor's diagnosis was for her to do more exercises and diet more. Her menstruation period increased in duration from 3 days, to 15 days. Which is an increase of 500%. The possible increase in acne was over her entire back, and portions of her chest, abdomen and buttocks. The acne would start about 7 days prior to her menstruation period and lasted about 7 days after her 15 day menstruation period. There was also a significant increase in body hair. 14 November 1991, my wife started feeling pain in the implant site and had debilitating headaches. She was given pain medication. The summer of 1992, my wife experienced weakness in her left arm, and numbness from her left elbow up to the implant site. She was also experiencing severe mood swings and irritability.

On 15 December 1992, my wife could no longer tolerate these major adverse side effects, and we had the 6 Norplant capsule surgically removed. What was supposed to have been a simple procedure was complicated by the fact that several of the Norplant capsules had migrated 4 inches down to the bottom side of her left arm, close to her elbow. The surgical procedure to remove the capsules was an extremely painful experience.

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STEPHEN K. CARTER


We agree with the Population Research Institute, Norplant has damaged so many women, in so many countries, my wife included, that it must be withdrawn from the market before it can damage any more. Please consider the Norplant petition with the greatest care. Wyeth Ayerst claims Norplant was tested on 55,000 women around the world, yet an estimated 50,000 are suing the company over the pain that their product caused. We may never know how many thousands of women from third world countries have suffered from the Norplant contraceptive because of their poverty or lack of legal rights and media outlets that women in the United States have. We urge the FDA to prevent more women around the world from needless victimization and take Norplant off the market.

Thank you for your time and consideration.

Sincerely,



Stephen K. Carter



Nohemi B. Carter

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